

# Foreign Direct Investment in Indian Pharmaceutical Industry: An Assessment

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**Abstract:** The Indian pharmaceutical sector has come a long way, being almost non-existent at the time of independence to a prominent provider of healthcare products, meeting almost all the pharmaceutical needs of the country. Over the years, India has become an attractive investment destination for FDI. The study undertakes the task of assessing the current scenario of FDI in the Pharmaceutical sector in India. With the help of available relevant secondary data, a qualitative approach was followed for the study. It was found that the major factors that are attracting FDI in pharmaceutical sector are: increase in domestic demand, rise in outsourcing activities, growth in healthcare financing products, demand in the generics market, demand from emerging segments, large numbers of forthcoming patent expiries, dry pipeline of new drugs. But simultaneously, there are some challenges which this pharmaceutical industry is facing, for example: low government expenditure on healthcare, inadequate investment in healthcare infrastructure rural areas, lack of proper policy framework to attract larger FDI in healthcare sector, especially in the area of research and development, focus on price-controlling policy, lack of robust policies governing IPRs, lack of data protection, bureaucratic hurdles. There might be more technology transfer in the future when the IPRs are protected. It is possible that under the new patent laws, MNCs will start to outsource even patented drugs in India; consequently there will be larger scope for technology transfer spillovers in the future. It is in the interest of the state to provide public policies and a sound economic environment to encourage benefit from FDI.

**Keywords:** Pharmaceutical, FDI, Pharma, India, U.S.

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## I. INTRODUCTION

The Indian pharmaceutical sector has come a long way, being almost non-existent at the time of independence to a prominent provider of healthcare products, meeting almost all the pharmaceutical needs of the country. According to [1], today the Indian pharmaceutical market is the 3<sup>rd</sup> largest in the world in terms of volume and 14<sup>th</sup> largest in terms of value. The annual turnover of the industry has already exceeded past Rs.1,00,000 Crore mark way back in the year 2009. Around 40% of the sales of the industry is coming through exports which shows the extent of penetration of Indian pharmaceutical companies in the global market. Pharmaceutical exports constitute more than 4% of the total national exports of our country. Moreover, the industry is growing at a respectable rate of around 10% annually with the projected growth rate rising to 18% by the year 2016-17. The Indian pharmaceutical industry is currently employing around 3.5 lakh employees of which a substantial share of employees are highly educated and skilled with Ph.D and M.Tech degrees.

However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in unorganized sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share. India is among the top 20 pharmaceutical exporting countries. Indian drugs are exported to around 200 countries in the world with highly regulated markets of USA, UK etc. The major therapeutic categories of export are anti infective, anti asthmatic and anti hypertensive [2].

The Indian pharmaceuticals market is witnessing dynamic changing trends such as large acquisitions by multinational companies in India, increasing investment by domestic and international players in India, deeper penetration into the rural

markets, growth and availability of healthcare and incentives for setting up special economic zones (SEZ's). Research & Development in India is getting more innovative. Domestic companies have strengthened their position in the world for supplying solutions across the pharmaceutical value chain. They are likely to become a competitor of global pharma in the areas of manufacturing and R&D, and a potential partner in others.

The Indian pharmaceutical industry has in the last five years seen half a dozen big takeovers by foreign companies. They include the \$3.6 billion acquisition of the promoters' stake in India's largest drug maker Ranbaxy Laboratories in 2008 by Japan's Daiichi Sankyo Co. Ltd. US drug maker Mylan Inc. paid \$734 million to acquire Hyderabad-based Matrix Laboratories in 2006. German health care group Fresenius SE spent \$219 million to take over Dabur Pharma in 2008. French drug multinational Sanofi-Aventis SA acquired a majority stake in Indian vaccines company Shanta Biotech in 2009 for €550 million. Last year, US drug and nutrition firm Abbott Laboratories paid \$3.72 billion to acquire Piramal Healthcare Ltd's domestic drug formulation business and spent \$726 million to buy out Ahmedabad-based consumer health company Paras Pharmaceuticals [3].

## II. FOREIGN DIRECT INVESTMENT IN PHARMACEUTICAL SECTOR

IMF defines FDI as the process whereby residents of one country (the home country) acquire ownership of assets for the purpose of controlling the production, distribution and other activities of a firm in another country (the host country). According to the Balance of Payment Manual-5, foreign direct investment is the category of international investment that reflects the objective of obtaining a lasting interest by a resident entity in one economy in an enterprise resident in another economy. As per UNCTAD, the lasting interest implies the existence of a long-term relationship between the direct investor and the enterprise and a significant degree of influence by the investor on the management of the enterprise. In Indian context FDI can be defined as investment by non-resident entity/person resident outside India in the capital of the Indian company under Schedule 1 of FEM (Transfer or Issue of Security by a Person Resident outside India) Regulations 2000 [4].

FDI normally enters an industry in the following three ways:

- a. Green field investment is when a company establishes a subsidiary in a new country and starts its own production.
- b. Brown field investment is FDI that involves the purchase of an existing plant or firm, rather than construction of a new plant.
- c. Joint venture is an equity and management partnership between the foreign firm and a local entity in the host market

### A. Routes of FDI in Indian Pharmaceutical Industry

According to guidelines issued by Reserve Bank of India [5], FDI in pharmaceutical industry in India is permitted by the following two routes:

1. Automatic route: This does not require any prior approval either by the government or the RBI. Under the existing policy, FDI is permitted up to 100% for Greenfield investments.
2. Prior Government Approval route: In this route, the FDI proposals are considered in a time-bound and transparent manner by the Foreign Investment Promotion Board (FIPB) under the Department of Economic Affairs, Ministry of Finance. Here also 100% FDI is permitted for investment in existing companies, i.e., brown field projects.

The Indian pharmaceutical industry has attracted US\$1707.52 million worth of foreign direct investment (FDI) in the period between April 2000 and April 2010. This FDI is exclusive of investments in shares of Indian firms. Acquisitions of local players by large MNCs illustrate the increasing level of interest that they have shown in the Indian market. MNC acquisitions in the Indian Pharma space took off in 2008 with the acquisition of Ranbaxy by Japanese drug maker, Daiichi Sankyo for US\$4.6 billion. This deal was valued at five times Ranbaxy's sales. Since then, there has been a trend of higher valuations of Indian Pharma companies. In 2010, Abbott Inc. bought Piramal Healthcare in a deal worth US\$3.7 billion, a valuation that was nine times the value of Piramal's sales revenue. Even though the global economy is currently facing one of its worst economic crises in the modern history, the Indian pharmaceutical industry is still an attractive investment destination for foreign investors [6].

***B. Factors Responsible for Constant Flow of FDI in Pharmaceutical Sector***

- Increase in domestic demand: Most of the Indian population has been deprived of the basic medical facilities till now, but with the growth in awareness and literacy levels of the general public the use of medicines has seen a sharp increase.
- Rise in outsourcing activities: Some of the factors that are likely to influence clinical data management and bio-statistics markets in India in the near future include: 1) cost efficient research vis-à-vis other countries 2) highly-skilled labour base 3) cheaper cost of skilled labour 4) presence in end-to-end solutions across the drug-development spectrum and 5) robust growth in the IT industry.
- Growth in healthcare financing products: Development in the Indian financial industry has eased healthcare financing with introduction of products such as health insurance policy, life insurance policy and cashless claims. This has resulted in increase in healthcare spending, which in turn, has benefitted the pharmaceutical industry.
- Demand in the generics market: During 2008-2015, prescription drugs worth about US\$ 300 billion are expected to go off patent, mostly from the US. Prior experience of Indian pharmaceutical companies in generic drugs would provide an edge to them [7].
- Demand from emerging segments: Some of the emerging segments such as contract research and development, biopharma, clinical trials, bio-generics, medical tourism and pharma packaging are also expected to drive growth of the Indian pharmaceutical industry.
- Patent Expiries: A large numbers of block buster drugs are going off patent in the coming 3-5 years and there are no revolutionary molecules in the pipeline for some years to come. This factor has put pressure on the global pharma giants to look beyond the North America, Europe and Japan for new growth opportunities.

Apart from these factors, the advantages offered by India in terms of economic reforms, cheaper labour cost, geographic closeness to source countries like China etc. have contributed towards attracting FDI in the pharmaceutical sector.

The production of pharmaceuticals is quite cheap in India and there is a strong production base in the country. It is easy to get good quality bulk drugs, which is attractive for foreign firms. Because of India's focus on reverse engineering and development of production processes India has acquired high technical competence in production of pharmaceuticals.

To add to its attractiveness, the Indian Department of Pharmaceuticals has prepared "Pharma Vision 2020" aimed at making India one of the leading destinations for end-to-end drug discovery and innovation through a state financed venture capital fund to improve pharma infrastructure, making India an attractive destination for pharmaceutical companies looking to escape cost pressure in mature economies.

As per the SWOT analysis conducted by the planning Commission [8] while preparing the 12<sup>th</sup> plan, the commission has found the following strengths and weaknesses of the Indian pharmaceutical industry:

Strengths:

- (a) Strong Low cost manufacturing sector
- (b) Significant breadth and depth of product expertise
- (c) Low cost of growing Human resources in the Pharma sector.

The major weaknesses are:

- (a) High emphasis on generics both for domestic and international markets where filing and approval of ANDAs and DMFs have left little room for R&D on drugs development
- (b) Inadequate R&D Infrastructure
- (c) Poor Industry-Academia linkage
- (d) Lack of required high-end product development capable human resources
- (e) Lack of time driven regulatory infrastructure
- (f) Poor SME base for high-end manufacture.

The major opportunities available are:

- (a) Global opportunity for increasing Generics and bio-generics market both in developed and emerging countries due to pressure on budgetary limitations of these countries as well as emergent patent cliff due to off patenting of major high-value drugs
- (c) Low cost good skill destination for contract research and manufacturing and resultant opportunities in drug discovery as well as clinical trials
- (d) High growth of domestic market attracting multi-nationals both for brown field and green field investments in production and capacity building.

The threats to the industry are from:

- (a) Ever-greening strategy of MNCs for denying and limiting the patent cliff opportunities with debatable recourse to TRIPs and FTAs
- (b) Increasingly stringent regulatory and non-tariff barriers to generics markets in developed countries
- (c) Increased competition for generics and bio-generics production in terms of high capacity and production costs
- (d) High-entry barriers to enable market share in development of new drugs.

### III. CHALLENGES AND POLICY FRAMEWORK OF FDI IN INDIA

The foreign investors willing to invest in Indian pharma industry are encountering the following challenges:

- Low government spend on healthcare (only 1 %).
- Inadequate investment in healthcare infrastructure especially in Tier II and rural Areas.
- Lack of proper policy framework to attract larger investments, including FDI, in healthcare sector, especially in the area of research and development.
- Policy focus highly centred on controlling prices rather than improving awareness and access.
- Lack of robust policies governing Intellectual Property Rights.
- The lack of data protection is another lacuna which deters prospective investors from investing in the India economy.
- Bureaucratic hurdles.

#### A. Government Policy on FDI in Pharmaceutical Sector

The Department of Pharmaceuticals has prepared “Pharma Vision 2020” for planned development of the pharmaceutical industry in India. The vision as stated by the department is to make India the Largest Global Provider of Quality Medicines at Reasonable Prices.

To achieve this vision the department proposes to follow the following mission:

- Develop Human Resources for Pharmaceutical Industry and Drug Research and Development
- Promote Public-Private Partnership for development of pharmaceuticals Industry
- Promote Pharma Brand India through International Cooperation
- Promote environmentally sustainable development of Pharmaceutical Industry
- Enable availability, accessibility and affordability of drugs

In order to facilitate the growth of pharmaceutical industry in the country, the Government of India has set the following goals in the 12<sup>th</sup> plan:

- Production size of US\$60bn and export size of over US\$25bn.
- Upgradation of SMEs to WHO-GMP and training of professionals therein.
- Establishment of Pharma Growth Clusters.
- Facilitate growth of Central pharma PSUs.
- Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation
- Develop Pharma Human Resources through increased M.Pharma and Ph.D programs in NIPERs
- Provide Infrastructure and staff for new NIPERs and strengthen NIPER Mohali

- Open 10 new NIPERs
- Jan Aushadi Campaign and implementation of Business Plan for setting up of 3000
- Jan Aushadhi Stores (upto Subdivision level in the country)
- Incentivizing Private Sector for development of new Drugs for diseases endemic to India

The Government of India has shown its intent and objective to promote foreign direct investment through a policy framework which is transparent, predictable, simple and clear and reduces regulatory burden.

A few major changes brought in after liberalization of the economy in 1991 are:

1. Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
2. Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb.1999, thus opening them up for manufacture by the private sector also.
3. Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has now been raised to 100%.
4. Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.
5. Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.
6. Extending the facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology.
7. Introduction of the Patents (Second Amendment) bill in the Parliament. It, inter-alia, provides for the extension in the life of a patent to 20 years.

The government convened a meeting of a high level committee involving certain ministries and government agencies on October 11, 2011 in which it was decided that FDI, in all brownfield projects in the pharma sector, will henceforth be scrutinised by the FIPB as an interim measure until the government comes up with a comprehensive policy to regulate such investments. However, the government has exempted FDI in Greenfield projects from any prior FIPB approval requirement. It has also been proposed that in future, all Brownfield investments will be scrutinised and approved by the Competition Commission of India [9].

#### **IV. SPILL-OVER EFFECTS OF FDI**

FDI is widely considered to be beneficial for the host economy since it can bring in transfer of technology, increased competition and imitation effects.

- Imitation Effect - The MNCs that bring in the FDI bring their proprietary technology, management and marketing skills. The domestic firms tend to observe these techniques and later imitate them.
- Imitation, reverse engineering and copying of foreign products or production processes bring in the spillover effects which are beneficial for the competition in the market.
- Increased competition forces less efficient domestic firms to take on more efficient production and lead to new innovations.
- FDI may also result in the breaking of monopoly or oligopoly in the industry.
- FDI brings in superior Training and development of employees across all levels. The Indian pharma industry employs a huge number of people directly and indirectly, who are benefited through this training.
- FDI in the contract research and manufacturing services of the pharma industry lead to increased domestic exports.

However the inflow of FDI can also bring in certain negative effects to the industry, such as:

- FDI meant for acquisitions of the existing domestic companies may sometimes lead to an innovative domestic company converting into a mere manufacturing facility for an MNC.
- In some cases the FDI flow may lead to increase in the prices of medicines due to reduced availability of generics in the market.
- Certain sections of the society believe that FDI in the pharma industry only works for the benefit of western markets thus depriving Indian consumers of low cost medicines.
- The MNCs may only bring in redundant or limited technology to the domestic industry at an early stage to increase production of drugs which are popular in the western countries.
- FDI may result in unfair competition that may prompt the domestic companies to abandon research for diseases such as malaria, which are relevant only for the developing nations. It may further lead to lesser research in the area of orphan drugs.

## V. ROAD AHEAD

McKinsey & Company's report [10] has predicted that the Indian pharmaceuticals market will grow to US\$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach to US\$70 billion by 2020. By 2015 it is expected to reach in the top 10 markets in terms of value beating Brazil, Mexico, South Korea and Turkey. More importantly, the incremental market growth of US\$ 14billion over the next decade is likely to be the third largest among all markets. The Market Research firm Cygnus' has forecasted that the Indian bulk drug industry will expand at an annual growth rate of 21 percent to reach \$16.91 billion by 2014.

Apart from mergers and acquisitions, the Indian pharmaceutical companies are also entering into long-term supply deals with innovators and generic producers to maximize their potential. Deals between Pfizer and Aurobindo pharma, GlaxoSmithKline and Dr. Reddy's Labs are some recent examples of out-licensing deals where generic makers are signing distribution and marketing contracts, so that their products reach foreign regulated markets. Due to the large number of drugs going off-patent in the next few years, this trend is expected to increase even further.

### A. Suggestions for Reaping in Maximum Benefits from FDI

It is now more or less established that the inflow of foreign investment in a sector brings in more positive effects for the country and the society at large. The need of the hour is to regulate the FDI flow in a manner so as to maximize the gains for the pharmaceutical sector while keeping the negatives to a bare minimum. For achieving this goal the following suggestions may prove to be very beneficial:

- The FDI policy in the sector needs to be harmonized keeping in sight the growing medical needs of our society. The FDI policy needs to be consistent. The foreign investors must have the faith that the FDI policy will sustain for a long duration. The past experience where the government has time and again sought to review the policy does not send a positive signal to the investors who wish to come of our country.
- The FDI policy should be formulated in a manner that would encourage drug discovery research and transfer of technology to improving R&D capabilities of our companies.
- The drug pricing policy should also be in harmony with the FDI policy so that the drugs can reach the maximum people and at the same time the pharmaceutical companies do not incur losses after undertaking long and arduous research.
- The patent laws and the regulatory frame work should be able to protect the R&D brought in by the MNCs by way of FDI.
- Data protection laws needs to be framed and implemented to protect the R&D data.
- The healthcare spend needs to be increased from the current 3% of GDP with a focus on improving healthcare infrastructure in the country.

Needless to say, the aforesaid suggestions can only be implemented by adopting a holistic approach wherein all the stakeholders including government play their part with honest intentions.



## VI. CONCLUSION

The Indian pharmaceutical industry will remain one of the fastest growing in the world for many more years to come. Indian pharmaceutical industry has established its own distinguished place in the world and is known to be the most cost effective supplier of quality drugs. A substantial portion of the population in the developing and under developed countries is dependant on this industry for even the most basic of needs.

The economic reforms coupled with stronger intellectual property protection laws are attracting the most advanced technologies and R&D taking place in the sector.

The foreign direct investment route is the fastest, safest and most effective mode of bringing in the new technology in the country. It is in the interest of the country to provide public policies which are transparent and consistent to instil confidence in the investors to bring in the most advanced and latest technologies to our country.

The "Pharma Vision 2020" conceived by the Department of Pharmaceuticals can be considered as a positive step in this direction. It is the need of the hour to attract more and more FDI in the pharmaceutical sector by creating a conducive investment environment in the country.

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